K120449 (pg 1/2)

MAY 11 2012

SECTION 2 - 510(k) SUMMARY

HEALIX ADVANCE™ PEEK Anchor

Submitter's Name and Address	DePuy Mitek *a Johnson & Johnson company* 325 Paramount Drive Raynham, MA 02767
Contact Person	Yayoi Fujimaki Regulatory Affairs Senior Associate DePuy Mitek, Inc. *a Johnson & Johnson company* 325 Paramount Drive Raynham, MA 02767, USA Telephone: 508-828-3541 Facsimile: 508-977-6911 e-mail: yfujima1@its.jnj.com
Name of Medical Device	Proprietary Name: HEALIX ADVANCE™ PEEK Anchor Classification Name: Smooth or threaded metallic bone fixation fasteners Common Name: Bone Anchor
Substantial Equivalence Facility	The HEALIX ADVANCE PEEK Anchor is substantially equivalent to: ▪ K071481: Healix PEEK Anchor
Device Classification	Smooth or threaded metallic bone fixation fasteners, classified as Class II, product code HWC, regulated under 21 CFR 888.3040.

Device Description	The HEALIX ADVANCE PEEK Anchor is non-absorbable threaded suture anchor manufactured of PEEK material. The anchor comes preloaded on a disposable inserter assembly and is intended for fixation of size 2 suture to bone. The suture options may include needles to facilitate suture passage through tissue. HEALIX ADVANCE PEEK Anchor is provided sterile and is for single patient use only.	
Indications for Use	**Shoulder:**	Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction;
	Foot/Ankle:	Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair;
	Knee:	Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis;
	Elbow:	Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction;
	Hip:	Capsular repair, Acetabular Labral Repair.
Safety and Performance	Non-clinical Testing Design verification activities, such as Anchor Torque and Anchor Pull Out were performed against pre-defined acceptance criteria according to the indicated use. Results of performance testing have demonstrated that the proposed devices are suitable for their intended use. Based on the indications for use, technological characteristics, and comparison to the predicate devices, the proposed HEALIX ADVANCE PEEK Anchor have shown to be substantially equivalent to the predicate devices under the Federal Food, Drug and Cosmetic Act.	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DePuy Mitek, Inc
a Johnson and Johnson Company
% Ms. Yayoi Fujimaki
Regulatory Affairs Senior Associate
325 Paramount Drive
Raynham, MA 02767

JUL - 2 2012

Re: K120449
Trade/Device Name: HEALIX ADVANCE™ PEEK Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: May 11, 2012
Received: May 11, 2012

Dear Ms. Fujimaki:

This letter corrects our substantially equivalent letter of May 11, 2012.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other

requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): K120449 (pg 1/1)

Device Name: HEALIX ADVANCE™ PEEK Anchor

Indications for Use:

The **HEALIX ADVANCE™ PEEK Anchor** is indicated for:

Shoulder:	Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction;
Foot/Ankle:	Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair;
Knee:	Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis;
Elbow:	Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction;
Hip:	Capsular repair, Acetabular Labral Repair.

Prescription Use ___x___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120449